

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P 04-128NH	<div style="display: flex; justify-content: space-between;"> <div>FOR FURTHER ACTION</div> <div>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</div> </div>	
International application No. PCT/SE 2004/000698	International filing date (<i>day/month/year</i>) 6 May 2004	(Earliest) Priority Date (<i>day/month/year</i>)
Applicant St. Jude Medical AB et al		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item:

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II)

3. ☐ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-26
because they relate to subject matter not required to be searched by this Authority, namely:

See next page
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Claims 1826 relate to a method of treatment of the human body by surgery or by therapy/ a diagnostic method practised on the human or animal body/Rule 39.1(1v). Nevertheless a search has been executed for these claims. The search has been based on the alleged effects of the device.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/02, A61N 1/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ, BIOSIS, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Lazar Mandinov et al Diastolic Heart failure Cardiovascular Research vol 45, no 4 (2000) 813-825 AN NLM 10728407 see page 814-818 --	1-26
A	Daniel J. Lenihan et al Mechanisms, diagnosis, and treatment of diastolic heart failure vol. 130, no. 1, 1995 AN NLM 7611107 see page 157, column 2 - page 159, column 2 --	1-26

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 November 2004

Date of mailing of the international search report

16-12-2004

Name and mailing address of the ISA/

Swedish Patent Office

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02053026 A2 (MEDTRONIC, INC), 11 July 2002 (11.07.2002), page 7, line 15 - page 8, line 11; page 22, line 14 - page 23, line 19; page 33, line 27 - page 37, line 25 --	1-26
A	WO 0243587 A1 (ST. JUDE MEDICAL AB), 6 June 2002 (06.06.2002), see whole document -----	1-26

INTERNATIONAL SEARCH REPORT
Information on patent family members

30/10/2004

International application No.

PCT/SE 2004/000698

WO	02053026	A2	11/07/2002	CA	2433359 A	11/07/2002
				EP	1347704 A	01/10/2003
				JP	2004523269 T	05/08/2004
				US	6738667 B	18/05/2004
				US	20030074029 A	17/04/2003
<hr/>						
WO	0243587	A1	06/06/2002	EP	1339320 A	03/09/2003
				SE	0004417 D	00/00/0000
				US	20040049238 A	11/03/2004

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

Groth & CO. KB
Box 6107
102 32 Stockholm

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference P 04-128NH		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/SE2004/000698	International filing date (day/month/year) 06-05-2004	Priority date (day/month/year) -	
International Patent Classification (IPC) or both national classification and IPC A61B 5/02, A61N 1/365			
Applicant St. Jude Medical AB et al			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Patent- och registreringsverket
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**WRITTEN OPINION OF THE
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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 18-26

because:

☒ the said international application, or the said claims Nos. 18-26
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 18-26 relate to a method of treatment of the human body by surgery or by therapy/ a diagnostic method practised on the human or animal body/Rule 67.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ The claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-17</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-17</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-17</u>	YES
	Claims		NO

2. Citations and explanations:

Documents cited in the International Search Report:

D1: Cardiovascular Research, Vol. 45, No. 4, March 2000, p. 813-825

D2: American Heart Journal, Vol. 130, No. 1, 1995, p.153-166

D3: WO 02 053 026 A2

D4: WO 02 43 587 A1

The cited documents represent the general state of the art. The invention defined in claims 1-17 is not disclosed by any of these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed apparatus for detecting diastolic heart failure. Therefore, the claimed invention is not obvious to a person skilled in the art.

Accordingly, the invention defined in claims 1-17 is novel and is considered to involve an inventive step. The invention is industrially applicable.